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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,368	08/06/2003	Kenneth Stewart	6714-46501	6917
23646 7590 12/23/2008 BARNES & THORNBURG LLP 750-17TH STREET NW SUITE 900 WASHINGTON, DC 20006-4675				
EXAMINER				
SHAFFER, RICHARD R				
ART UNIT		PAPER NUMBER		
3775				
MAIL DATE		DELIVERY MODE		
12/23/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/634,368

Applicant(s)

STEWART, KENNETH

Examiner

Richard Shaffer

Art Unit

3775

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
4a) Of the above claim(s) 35 and 37 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 23-34, 36 and 38-41 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29 recites the limitation "the hollow cap **encapsulates substantially all** of the bone instrumentation which projects from bone."

There is no disclosure or inherency as originally filed that the hollow cap encapsulates substantially all of the bone instrumentation which projects from bone.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-28 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites "a second suture string" with no appreciable claimed difference compared to a "plurality of first suture strings" as set forth in claim 25. Therefore, it is unclear where there are "second suture strings" with essentially the same properties as a "plurality of first suture strings." Claims 27 and 28 fail to correct for the deficiency.

Claim Rejections - 35 USC § 101

The amendments to the claims filed on September 4th, 2008 are acknowledged and accepted by the examiner. The previous 35 U.S.C. 101 rejections have been overcome and are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-34, 36, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellman (US Patent 4,428,375).

Ellman discloses a device (**Figures 1-4**) comprising: a hollow cap (**15**) made of absorbable Dacron™ (**Column 2, Lines 30-40**) and capable of removal in a subsequent surgical procedure; a separate tubular cinch ring (**20 and 22 together**) having openings (one opening defined by the enclosed circles of **either 20 or 22**; a second opening defined by the space between **20 and 22** – same opening direction as those of **19**); adjustable sutures (**16**) of the cap (**15**) are "threaded" through the openings of the cinch ring; [**First Interpretation**] a non-adjustable (as in same direction as adjustable) suture (**21**) tied to the lower edge of the cap and attached to the cinch ring; [**Second Interpretation**] a drawstring (**21**) within the cinch ring to circumferentially tighten the hollow cap.

Claims 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Harms et al (US Patent 4,820,305).

Harms et al disclose (**Figure 4**) a combination comprising: a pedicle screw (**14**) and a barrier material (**1**) covering a portion of the pedicle screw. The barrier material is a medically safe physical barrier between the pedicle screw and surrounding soft tissue.

Response to Arguments

Applicant's arguments filed on September 4th, 2008 have been fully considered but they are not persuasive.

In regard to the 35 U.S.C. 112, first paragraph rejection, it is not persuasive that applicant argued possession of a device that is dimensioned to be placed over and to encapsulate projecting parts as reasonably disclosing the limitation "encapsulating substantially all of the bone instrumentation which projects from bone." As the disclosure applicant himself cited, all that is supported by the specification as originally filed is that the cap/casing can be placed over certain projecting parts, not substantially all of the projecting parts and not necessarily substantially all of any given part.

In regard to applicant's 35 U.S.C. 112, second paragraph remarks, applicant appears confused as to the issue of claim 26. It was **stated that the claimed limitation** had no appreciable difference in relation to claim 25. It matters not if applicant can point out distinct differences in the specification, rather that the claimed limitation is indefinite because it is not understood what claim 26 actually adds to the limitations already set forth in claim 25.

In regard to applicant's remarks in relation to the 35 U.S.C. 102 (b) rejections as being anticipated by Ellman stating that Ellman fails to disclose a medically safe barrier. A barrier is a rather broad term, as the mesh network clearly would prevent any soft tissue larger than an opening from passing through as clearly depicted in Figures 3 and 4.

Conclusion

Applicant's amendment adding claims 40 and 41 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/
Examiner, Art Unit 3775
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733